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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/064,627	07/31/2002	Mohsen Shahinpoor	GED-1	8855
27232	7590	10/26/2004	EXAMINER	
MOHSEN SHAHINPOOR 909 VIRGINIA, NE, SUITE 205 ALBERQUERQUE, NM 87108			WEDDINGTON, KEVIN E	
			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 10/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/064,627

Applicant(s)

SHAHINPOOR ET AL.

Examiner

Kevin E. Weddington

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 3-13, 17 and 18 ~~is/are withdrawn from consideration~~ *will not be examined*.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 14-16 and 19-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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CLAIMS 1-23 ARE PRESENTED FOR EXAMINATION.

APPLICANTS' ELECTION FILED JULY 9, 2004 IN RESPONSE TO THE ELECTION OF SPECIES REQUIREMENT OF JUNE 18, 2004 HAS BEEN RECEIVED AND ENTERED. THE APPLICANTS ELECTED THE SPECIES FROM THE NO RELEASING AGENT, PYRIMIDINE (MINOXIDIL), AND THE cGMP-PDE5 INHIBITOR, SILDENAFIL CITRATE.

CLAIMS 3-13, 17 AND 18 WILL NOT BE EXAMINED WITH THE REMAINING CLAIMS SINCE THE CLAIMS ARE REFERRED TO NON-ELECTED SPECIES.

*SPECIFICATION*

THE USE OF THE TRADEMARKS ROGAIN AND VIAGRA HAS BEEN NOTED IN THIS APPLICATION. IT SHOULD BE CAPITALIZED WHEREVER IT APPEARS AND BE ACCOMPANIED BY THE GENERIC TERMINOLOGY.

ALTHOUGH THE USE OF TRADEMARKS IS PERMISSIBLE IN PATENT APPLICATIONS, THE PROPRIETARY NATURE OF THE MARKS SHOULD BE RESPECTED AND EVERY EFFORT MADE TO PREVENT THEIR USE IN ANY MANNER WHICH MIGHT ADVERSELY AFFECT THEIR VALIDITY AS TRADEMARKS.

*CLAIM REJECTIONS - 35 USC § 112*

THE FOLLOWING IS A QUOTATION OF THE FIRST PARAGRAPH OF 35 U.S.C. 112:

THE SPECIFICATION SHALL CONTAIN A WRITTEN DESCRIPTION OF THE INVENTION, AND OF THE MANNER AND PROCESS OF MAKING AND USING IT, IN SUCH FULL, CLEAR, CONCISE, AND EXACT TERMS AS TO ENABLE ANY PERSON SKILLED IN THE ART TO WHICH IT PERTAINS, OR WITH WHICH IT IS MOST NEARLY CONNECTED, TO MAKE AND USE THE SAME AND SHALL SET FORTH THE BEST MODE CONTEMPLATED BY THE INVENTOR OF CARRYING OUT HIS INVENTION.

CLAIM 20 IS REJECTED UNDER 35 U.S.C. 112, FIRST PARAGRAPH, AS FAILING TO COMPLY WITH THE ENABLEMENT REQUIREMENT. THE CLAIM(S) CONTAINS SUBJECT MATTER WHICH WAS NOT DESCRIBED IN THE SPECIFICATION IN SUCH A WAY AS TO ENABLE ONE SKILLED IN THE ART

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TO WHICH IT PERTAINS, OR WITH WHICH IT IS MOST NEARLY CONNECTED, TO MAKE AND/OR USE THE INVENTION.

APPLICANTS' SPECIFICATION DOES NOT CONTAIN REFERENCE REGARDING THE ADDITION OF ONE OR MORE ANTIMICROBIAL AGENTS TO THE TOPICAL OPHTHALMIC SOLUTION.

CLAIM 20 IS NOT ALLOWED.

*CLAIM REJECTIONS - 35 USC § 112*

THE FOLLOWING IS A QUOTATION OF THE SECOND PARAGRAPH OF 35 U.S.C. 112:

THE SPECIFICATION SHALL CONCLUDE WITH ONE OR MORE CLAIMS PARTICULARLY POINTING OUT AND DISTINCTLY CLAIMING THE SUBJECT MATTER WHICH THE APPLICANT REGARDS AS HIS INVENTION.

CLAIMS 14 AND 16 ARE REJECTED UNDER 35 U.S.C. 112, SECOND PARAGRAPH, AS BEING INDEFINITE FOR FAILING TO PARTICULARLY POINT OUT AND DISTINCTLY CLAIM THE SUBJECT MATTER WHICH APPLICANT REGARDS AS THE INVENTION.

CLAIMS 14 AND 16 ARE RENDERED INDEFINITE BECAUSE THE CLAIMS CONTAIN TRADEMARK NAME, IN WHICH, TRADEMARK NAMES CANNOT BE USED IN A CLAIM.

CLAIMS 14 AND 16 ARE NOT ALLOWED.

TO OVERCOME THIS REJECTION, THE APPLICANTS MAY WISH TO AMEND CLAIMS 14 AND 16 BY DELETING THE TRADEMARK (ROGAIN) FROM CLAIM 14 AND DELETING THE TRADEMARK (VIAGRA) FROM CLAIM 16.

*CLAIM REJECTIONS - 35 USC § 112*

THE FOLLOWING IS A QUOTATION OF THE SECOND PARAGRAPH OF 35 U.S.C. 112:

THE SPECIFICATION SHALL CONCLUDE WITH ONE OR MORE CLAIMS PARTICULARLY POINTING OUT AND DISTINCTLY CLAIMING THE SUBJECT MATTER WHICH THE APPLICANT REGARDS AS HIS INVENTION.

CLAIMS 21 AND 23 ARE REJECTED UNDER 35 U.S.C. 112, SECOND PARAGRAPH, AS BEING INDEFINITE FOR FAILING TO PARTICULARLY POINT OUT AND DISTINCTLY CLAIM THE SUBJECT MATTER WHICH APPLICANT REGARDS AS THE INVENTION.

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CLAIM 21 RECITES THE LIMITATION "SAID DOSE" IN LINE 1. THERE IS INSUFFICIENT ANTECEDENT BASIS FOR THIS LIMITATION IN THE CLAIM.

CLAIM 23 RECITES THE LIMITATION "SAID ONE OR MORE WEIGHT PERCENTAGE" IN LINE 2. THERE IS INSUFFICIENT ANTECEDENT BASIS FOR THIS LIMITATION IN THE CLAIM.

CLAIMS 21 AND 22 ARE NOT ALLOWED.

*CLAIM REJECTIONS - 35 USC § 103.*

THE FOLLOWING IS A QUOTATION OF 35 U.S.C. 103(A) WHICH FORMS THE BASIS FOR ALL OBVIOUSNESS REJECTIONS SET FORTH IN THIS OFFICE ACTION:

(A) A PATENT MAY NOT BE OBTAINED THOUGH THE INVENTION IS NOT IDENTICALLY DISCLOSED OR DESCRIBED AS SET FORTH IN SECTION 102 OF THIS TITLE, IF THE DIFFERENCES BETWEEN THE SUBJECT MATTER SOUGHT TO BE PATENTED AND THE PRIOR ART ARE SUCH THAT THE SUBJECT MATTER AS A WHOLE WOULD HAVE BEEN OBVIOUS AT THE TIME THE INVENTION WAS MADE TO A PERSON HAVING ORDINARY SKILL IN THE ART TO WHICH SAID SUBJECT MATTER PERTAINS. PATENTABILITY SHALL NOT BE NEGATED BY THE MANNER IN WHICH THE INVENTION WAS MADE.

THIS APPLICATION CURRENTLY NAMES JOINT INVENTORS. IN CONSIDERING PATENTABILITY OF THE CLAIMS UNDER 35 U.S.C. 103(A), THE EXAMINER PRESUMES THAT THE SUBJECT MATTER OF THE VARIOUS CLAIMS WAS COMMONLY OWNED AT THE TIME ANY INVENTIONS COVERED THEREIN WERE MADE ABSENT ANY EVIDENCE TO THE CONTRARY. APPLICANT IS ADVISED OF THE OBLIGATION UNDER 37 CFR 1.56 TO POINT OUT THE INVENTOR AND INVENTION DATES OF EACH CLAIM THAT WAS NOT COMMONLY OWNED AT THE TIME A LATER INVENTION WAS MADE IN ORDER FOR THE EXAMINER TO CONSIDER THE APPLICABILITY OF 35 U.S.C. 103(C) AND POTENTIAL 35 U.S.C. 102(E), (F) OR (G) PRIOR ART UNDER 35 U.S.C. 103(A).

CLAIMS 1, 2, 19 AND 20 ARE REJECTED UNDER 35 U.S.C. 103(A) AS BEING UNPATENTABLE OVER NATHANSON (JOURNAL OF PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS (1992), 260(3), 956065) IN VIEW OF LATIES (EP 1,074,258 A2).

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NATHANSON TEACHES NITROVASODILATORS OR NITRIC OXIDE (NO) RELEASING AGENTS, SUCH AS ISOSORBIDE DINITRATE, SODIUM NITRITE, HYDRALAZINE, MINOXIDIL AND SODIUM NITROPRUSSIDE, MIMICKED THE LOWERING INTRAOCULAR PRESSURE ACTION OF NITROGLYCERIN. ALSO NOTE THE AGENTS ARE ADMINISTERED TOPICALLY, SAME AS APPLICANTS' MODE OF ADMINISTRATION. SINCE THE NITROVASODILATORS OF THE CITED REFERENCE IS KNOWN TO LOWER INTRAOCULAR PRESSURE OF THE EYE, THEN TO USE THE NITROVASODILATORS TO TREAT GLAUCOMA (A DISEASE CAUSED BY INCREASED INTRAOCULAR PRESSURE) OR OCULAR HYPERTENSION IS OBVIOUS.

THE INSTANT INVENTION DIFFERS FROM THE CITED REFERENCE IN THAT THE CITED REFERENCE DOES NOT TEACH THE ADDITION OF cGMP-PDE5 INHIBITORS TO LOWER OCULAR HYPERTENSION (GLAUCOMA). HOWEVER, THE SECONDARY REFERENCE, LATIES, TEACHES VARIOUS cGMP-PDE5 INHIBITORS ARE WELL-KNOWN TO TREAT DISEASES AND CONDITIONS OF THE EYE INCLUDING GLAUCOMA (SEE COLUMN 3, LINES 36-58 AND COLUMN 4, LINES 1-29). CLEARLY, ONE SKILLED IN THE ART WOULD HAVE ASSUMED THE COMBINATION OF TWO COMPONENTS USED TO TREAT ELEVATED INTRAOCULAR PRESSURE INTO A SINGLE COMPOSITION WOULD GIVE AN ADDITIVE EFFECT IN THE ABSENCE OF EVIDENCE TO THE CONTRARY. NOTE PARTICULARLY COLUMN 10, LINES 6-56 TEACHES THE cGMP-PDE5 INHIBITORS ARE ADMINISTERED IN SOLUTIONS FOR TOPICAL EYE DROPS.

NOTE BOTH REFERENCES EACH COMPONENT, THE NITROVASODILATORS AND THE cGMP-PDE5 INHIBITORS CAN BE ADMINISTERED IN A SOLUTION.

CLAIMS 1, 2, 19 AND 20 ARE NOT ALLOWED.

*CLAIM REJECTIONS - 35 USC § 103*

THE FOLLOWING IS A QUOTATION OF 35 U.S.C. 103(A) WHICH FORMS THE BASIS FOR ALL OBVIOUSNESS REJECTIONS SET FORTH IN THIS OFFICE ACTION:

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(A) A PATENT MAY NOT BE OBTAINED THOUGH THE INVENTION IS NOT IDENTICALLY DISCLOSED OR DESCRIBED AS SET FORTH IN SECTION 102 OF THIS TITLE, IF THE DIFFERENCES BETWEEN THE SUBJECT MATTER SOUGHT TO BE PATENTED AND THE PRIOR ART ARE SUCH THAT THE SUBJECT MATTER AS A WHOLE WOULD HAVE BEEN OBVIOUS AT THE TIME THE INVENTION WAS MADE TO A PERSON HAVING ORDINARY SKILL IN THE ART TO WHICH SAID SUBJECT MATTER PERTAINS. PATENTABILITY SHALL NOT BE NEGATED BY THE MANNER IN WHICH THE INVENTION WAS MADE.

THIS APPLICATION CURRENTLY NAMES JOINT INVENTORS. IN CONSIDERING PATENTABILITY OF THE CLAIMS UNDER 35 U.S.C. 103(A), THE EXAMINER PRESUMES THAT THE SUBJECT MATTER OF THE VARIOUS CLAIMS WAS COMMONLY OWNED AT THE TIME ANY INVENTIONS COVERED THEREIN WERE MADE ABSENT ANY EVIDENCE TO THE CONTRARY. APPLICANT IS ADVISED OF THE OBLIGATION UNDER 37 CFR 1.56 TO POINT OUT THE INVENTOR AND INVENTION DATES OF EACH CLAIM THAT WAS NOT COMMONLY OWNED AT THE TIME A LATER INVENTION WAS MADE IN ORDER FOR THE EXAMINER TO CONSIDER THE APPLICABILITY OF 35 U.S.C. 103(C) AND POTENTIAL 35 U.S.C. 102(E), (F) OR (G) PRIOR ART UNDER 35 U.S.C. 103(A).

CLAIMS 14-16 ARE REJECTED UNDER 35 U.S.C. 103(A) AS BEING UNPATENTABLE OVER NATHANSON (JOURNAL OF PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS (1992), 260(3), 956-65) IN VIEW OF SCHEMAN (US 2003/0225101 A1).

NATHANSON TEACHES NITROVASODILATORS, SUCH AS MINOXIDIL, ARE WELL-KNOWN TO LOWER INTRAOCULAR PRESSURE, IN WHICH, WILL TREAT OCULAR HYPERTENSION OF GLAUCOMA (A DISEASE CAUSED BY INCREASED INTRAOCULAR PRESSURE).

THE INSTANT INVENTION DIFFERS FROM THE CITED REFERENCE IN THAT THE CITED REFERENCE DOES NOT TEACH THE ADDITION OF SILDENAFIL OR SILDENAFIL CITRATE TO TREAT OCULAR HYPERTENSION (GLAUCOMA). HOWEVER, THE SECONDARY REFERENCE, SCHEMAN TEACHES SILDENAFIL IS EFFECTIVE IN TREATING DISEASES OF THE EYE. NOTE PARTICULARLY PAGE 1, SECTION 0012 STATES THE ONE CONDITION TREAT IN ISCHEMIC RVO AND THE RESULTING NEOVASCULARIZATION CAN LEAD TO INCREASED EYE PRESSURE (GLAUCOMA).

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CLEARLY, ONE SKILLED IN THE ART WOULD HAVE ASSUMED TO COMBINATION OF TWO AGENTS KNOWN TO LOWER INTRAOCULAR PRESSURE OF THE EYE INTO A SINGLE COMPOSITION WOULD GIVE AN ADDITIVE EFFECT IN THE ABSENCE OF EVIDENCE TO THE CONTRARY.


THE INSTANT INVENTION DIFFERS FROM THE CITED REFERENCE IN THAT THE CITED REFERENCE DOES NOT TEACH Sildenafil CITRATE CAN BE USED TOO. HOWEVER, ONE SKILLED IN THE ART WOULD HAVE ASSUMED THAT IF THE Sildenafil COMPOUND ITSELF IS KNOWN TO LOWER INTRAOCULAR PRESSURE THEN ITS SALTS INCORPORATES THE SAME ACTIVITY.

CLAIMS 14-16 ARE NOT ALLOWED.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO KEVIN E. WEDDINGTON WHOSE TELEPHONE NUMBER IS (571) 272-0587. THE EXAMINER CAN NORMALLY BE REACHED ON 11:00 AM-7:30 PM.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, CHRISTOPHER LOW CAN BE REACHED ON (571) 272-0953. THE FAX PHONE NUMBER FOR THE ORGANIZATION WHERE THIS APPLICATION OR PROCEEDING IS ASSIGNED IS 703-872-9306.

INFORMATION REGARDING THE STATUS OF AN APPLICATION MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE [HTTP://PAIR-DIRECT.USPTO.GOV](http://PAIR-DIRECT.USPTO.GOV). SHOULD YOU HAVE QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM, CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE).

  
KEVIN E. WEDDINGTON  
PRIMARY EXAMINER  
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K. WEDDINGTON

OCTOBER 20, 2004